



07-02-04

IFW

Attorney Docket No. 5405-280

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Koeberl et al.

Application No. 10/761,530

Filed: January 21, 2004

For: IMPROVED CONSTRUCTS FOR EXPRESSING LYSOMAL POLYPEPTIDES

Date: July 1, 2004

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Sir:

Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the waiver by the U.S. Patent and Trademark Office of requirements under 37 C.F.R. § 1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003. It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP.

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(b), within three months of the filing date of the above-referenced application or before the mailing of a first Office Action on the merits, whichever event occurs last. Therefore, no fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

  
Karen A. Magri  
Registration No. 41,965



Inventor: Koeberl et al.  
Application No. 10/761,530  
Filed: January 21, 2004  
Page 2 of 2

**Customer No. 20792**

Myers Bigel Sibley & Sajovec, P.A.  
P. O. Box 37428  
Raleigh, North Carolina 27627  
Telephone: (919) 854-1400  
Facsimile: (919) 854-1401

**CERTIFICATE OF EXPRESS MAILING**

"Express Mail" mailing label number: EV381443058US      Date of Deposit: July 1, 2004  
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sarah Brunmeier  
Sarah Brunmeier

<b>FORM PTO-1449 U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>				<b>Attorney Docket Number</b> 5405.280		<b>Serial No.</b> 10/761,530	
<b>LIST OF DOCUMENTS CITED BY APPLICANT</b>  (Use several sheets if necessary)  A1 of A1				<b>Applicants:</b> Dwight D. Koeberl			
<b>Filing Date:</b> January 21, 2004				<b>Group:</b> TBN			
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
1.	US-6,328,958		Amalfitano et al.				
2.	US-6,582,692		Podsakoff et al.				
3.	US-2003/0219414		Podsakoff et al.				
<b>FOREIGN PATENT DOCUMENTS</b>							
Document Number	Date	Country	Class	Subclass	Translation Yes   No		
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
4.	BARASH et al., "Human secretory signal peptide description by hidden Markov model and generation of a strong artificial signal peptide for secreted protein expression," <i>Biochemical and Biophysical Research Communications</i> <b>294</b> : 835-842 (2002).						
5.	CHENG et al., "Gene therapy progress and prospects: gene therapy of lysosomal storage disorders," <i>Gene Therapy</i> <b>10</b> : 1275-1281 (2003).						
6.	FRAITES et al., "Correction of the enzymatic and functional deficits in a model of pompe disease using adeno-associated virus vectors," <i>Molecular Therapy</i> <b>5</b> : 571-578 (May 2002).						
7.	HIRSCHHORN et al., "Glycogen Storage disease type II: acid $\alpha$ -glucosidase (acid maltase) deficiency," Wonsiewicz M, Noujaim S, Boyle P, eds, <i>The Metabolic and Molecular Bases of Inherited Disease</i> , 8 <sup>th</sup> Edition. New York: McGraw Hill; 2001, 3389-3420.						
8.	KOEBERL et al., "Development of a hybrid adenovirus/adeno-associated virus for gene therapy in glycogen storage disease type II." Abstract presented at the Annual Meeting of the Pediatric Academic Societies; Seattle, WA (May 3 - 6, 2003)						
9.	LIN et al., "Adeno-associated virus-mediated transfer of human acid maltase gene results in a transient reduction of glycogen accumulation in muscle of Japanese quail with acid maltase deficiency," <i>Gene Therapy</i> <b>9</b> : 554-563 (2002).						
10.	MARTIN-TOUAUX et al., "Muscle as a putative producer of acid $\alpha$ glucosidase for glycogenosis type II gene therapy," <i>Human Molecular Genetics</i> <b>11</b> :14 1637-1645 (2002).						
11.	RABEN et al., "Enzyme replacement therapy in the mouse model of Pompe disease," <i>Molecular Genetics and Metabolism</i> <b>80</b> : 159-169 (2003).						
12.	SUN et al., "Correction of glycogen storage disease type II (GSD II) by intramuscular administration of an adeno-associated virus (AAV) vector pseudotyped as AAV6," Abstract presented at the 6 <sup>th</sup> Annual Meeting of the American Society for Gene Therapy; Washington, D.C. (June 4 - 8, 2003).						
13.	SUN et al., "Long-term correction of glycogen storage disease type II with a hybrid Ad-AAV vector," <i>Molecular Therapy</i> <b>7</b> :2 193-201 (2003).						
14.	SUN et al., "Packaging of an AAV vector encoding human acid $\alpha$ -glucosidase for gene therapy in glycogen storage disease type II with a modified hybrid adenovirus-AAV vector," <i>Molecular Therapy</i> <b>7</b> : 4 467-477 (2003).						
15.	WISSELAAR et al., "Structural and functional changes of lysosomal acid $\alpha$ glucosidase during intracellular transport and maturation," <i>Journal of Biological Chemistry</i> <b>268</b> :3 2223-2231 (1993).						

 EXAMINER  
 \*EXAMINER

DATE CONSIDERED

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.